



Office for Human Research Protections  
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August 3, 2004

Albert Carnesale, Ph.D.  
Chancellor  
University of California, Los Angeles  
2147 Murphy Hall, Box 951405  
Los Angeles, CA 90095-1405

**RE: Human Research Subject Protections Under Federalwide Assurances (FWA) 4642**

**Activities Involving the Graduation Questionnaire (GQ)**

Dear Dr. Carnesale:

The Office for Human Research Protections (OHRP) has reviewed your report of October 30, 2003 regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced activities conducted at the University of California, Los Angeles (UCLA).

OHRP makes the following determinations about the above-referenced activities:

(1) HHS regulations at 45 CFR 46.116 require that procedures for enrolling subjects minimize the possibility of coercion or undue influence. It was alleged that many of the schools that recruit subjects for this research make participation in the research a requirement for graduation from medical school.

**Corrective Action:** OHRP acknowledges UCLA's statement that the only human subject research using GQ data conducted at UCLA was exempt. OHRP also acknowledges that UCLA may still require medical students to complete the GQ survey for program evaluation purposes but they will have a choice as to whether their identifiable data may be used for research.

(2) In accordance with HHS regulations at 45 CFR 46.103(b) and 46.109(a), the institutional review board (IRB) must review and approve all non-exempt human subject research covered by an assurance. It was alleged that human subject research involving the GQ was conducted without IRB review.

**Corrective Action:** OHRP acknowledges that the UCLA IRB has received requests for exemptions for some individual projects involving the use of GQ data. In addition, the GQ will be submitted to the AAMC IRB for review prior to its next administration.

(3) HHS regulations at 45 CFR 46.116 state that, except as provided elsewhere in the regulations, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. It was alleged that the institutions initiated human subjects research without meeting this requirement.

**Corrective Action:** OHRP acknowledges that AAMC will provide an opportunity for medical students completing the GQ to provide specific informed consent about whether or not the AAMC may retain their GQ data in a personally identifiable form for research purposes.

(4) HHS regulations at 45 CFR 46.111(a) state that, in order to approve research covered by the regulations, the IRB shall determine that certain requirements are satisfied. It was alleged that this research failed to satisfy the following requirements:

- (a) Risks to subjects are minimized.
- (b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- (c) Selection of subjects is equitable.
- (d) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

OHRP finds that this allegation could not be substantiated.

OHRP finds that the corrective actions above adequately address the concerns raised about the above-referenced activities and are appropriate under the UCLA FWA. As a result of the above determinations, OHRP sees no need for further involvement in this matter.

OHRP appreciates the continued commitment of your institutions to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.  
Director  
Division of Compliance Oversight

cc: Ms. Judith L. Brookshire M.S., Director, OPRS, U California, Los Angeles

Dr. Carmine, Clemente, Chair, IRB #1, U California, Los Angeles

Dr. Robert Figlin, Chair, IRB #2, U California, Los Angeles

Dr. Nancy Levine, Chair, IRB #3, U California, Los Angeles

Dr. Bernard Schwetz, OHRP

Dr. Melody H. Lin, OHRP

Dr. Michael Carome, OHRP

Ms. Janice Walden, OHRP

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